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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER MAEWALL, SNIGDEHA				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/724,826

Applicant(s)

SIMONNET ET AL.

Examiner

Snigdha Maewall

Art Unit

1612

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 and 44-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Receipt of Applicants' amendments, remarks filed on 12/19/08 and arguments and declaration filed on 12/19/08 is acknowledged.

Claims **25-43** are being examined on the merits herein.

The rejections or objections not reiterated herein have been withdrawn in view of applicant's arguments.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 25-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al. (US 5,753,241), in view of Tabibi et al. (US 5,130,122) and Kenji et al. (Journal of colloid and Interface science 236, 14-19 (2001) as evidenced by Nguyen et al. (US 6,669,849).

Ribier et al. teach an oil-in-water nanoemulsion, in which the oil globules are less than 100 nm, and contain an amphiphilic lipid component (abstract). The amount of oil ranges from 5 to 30% by weight with respect to the total weight of the emulsion (column 3, lines 16-18). The oil can be silicone oil, namely decamethylcyclopentasiloxane,

which has a molecular weight of 370.78 (column 3, line 47). The oil can also be Jojoba oil, which contains 36 to 46 carbons, and has a molecular weight of at least 432 (column 5, example 1; and wikipedia.org). Jojoba oil makes up 50% of the oils having a molecular weight greater than 400 (column 5, example 1).

Furthermore, Ribier et al. teach ionic amphiphilic lipids in the nanoemulsions, which can be alkaline salts of dicetyl and dimyristyl phosphate, alkaline salts of cholesterol sulphate, alkaline salts of cholesterol phosphate, sodium salts of phosphatidic acid, phospholipids, or alkylsulfonic derivatives (columns 2, lines 57-65; and column 3, lines 1-3). The ionic amphiphilic lipids are from 2 to 10% by weight (column 3, line 13).

Ribier et al. also teach emulsions that contain additives to improve the transparency of the formulation, such as lower alcohols and are 5 to 20% by weight (column 3, lines 49-51, 53, and 62).

Ribier et al. also teach the nanoemulsion for topical use such as a cosmetic or dermatopharmaceutical composition and for use on the eyes (column 4, lines 45-49). Since the nanoemulsion of Ribier et al. is for ophthalmic use (e.g. use on the eyes), it would be obvious that such a nanoemulsion contains an ophthalmic vehicle.

Ribier et al. do not teach nanoemulsions containing the surfactants herein and the turbidity of the nanoemulsion.

Tabibi et al. teach a submicron emulsion of adsorptive oil that contains surfactants (column 6, lines 58-59 and 62). The adsorptive oil may be from vegetable

oils, mineral oils, or animal oils (column 2, lines 33-35). The submicron emulsions are less than about 0.3 microns in diameter (column 4, lines 13-15).

Tabibi et al. do not specifically name surfactants however, it would be obvious that the surfactants of Tabibi et al. may include sucrose distearate as recited in claims 30 and 31 and other surfactants that are solids at a temperature of less than or equal to 45°C.

As evidenced by Nguyen et al., Nguyen et al. disclose a process for the removal of dissolved organic carbon from water (abstract). The organic carbon compounds in various water samples were coagulated, by addition of a coagulant, to form a floc, which can then be physically removed (column 1, lines 29-32). The turbidity of water samples where the floc size is 1-2 mm is 3.6 NTU (column 13, Table 2). Thus, the nanoemulsions of less than 100nm in the instant application are reasonably expected to have a turbidity measurement of 60 to 600 NTU as recited in instant claim 26.

Accordingly, absent the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the nanoemulsions of Ribier et al. to contain a surfactant because the submicron emulsions of Tabibi et al. contain a surfactant and according to Tabibi et al., submicron emulsions or nanoemulsions contain a surfactant.

The motivation to combine the nanoemulsion of Ribier et al. to the submicron emulsions of Tabibi et al. is that the submicron emulsions of Tabibi et al. contain a surfactant.

Regarding the amount of surfactant as recited in the instant claims 25 and 27-28, it is noted that Tabibi et al. teach submicron emulsions of adsorptive oils contain surfactants but the concentration of such surfactants were not disclosed (column 6, lines 58-59 and 62). Thus Tabibi et al. do teach the presence of a surfactant, which closely meets the amount of surfactant set forth in instant claims 25 and 27-28. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of surfactant provided in a composition, according to the guidance set forth in Tabibi et al., to provide a composition having desired amount of surfactant. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the ratio by weight of the amount of oily phase to the amount of surfactant as recited in instant claim 28, Ribier et al. teach the amount of oil ranges from 5 to 30% by weight with respect to the total weight of the emulsion (column 3, lines 16-18). Tabibi et al. teach submicron emulsions of adsorptive oils contain surfactants but the concentration of such surfactants was not disclosed (column 6, lines 58-59 and 62). Since Ribier et al. teach the amount of oil ranges from 5 to 30% by weight and Tabibi et al. teach the presence of surfactants, it would be obvious that the amount of surfactant present may yield a ratio of amount of oily phase to the amount of surfactant of 3 to 6 as recited in instant claim 28.

However, Kenji et al. specifically teach effect of adding amphiphilic solubilization improver, sucrose distearate on the solubilization capacity of nonionic microemulsions. (title and whole article). It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to incorporate specific surfactant in the teachings of combination of references and come to the claimed invention because it helps in solubilization, with a reasonable expectation of success.

Response to Arguments

4. Applicant's arguments filed 12/19/08 have been fully considered but they are not persuasive.

Applicant argues that none of the applied art teaches or suggests adding the required solid surfactants to nanoemulsions having at least one oil having a molecular weight of greater than 400. The Office Action recognized that Ribier I does not disclose the claimed surfactant. Similarly, the Office Action recognized that Tabibi neither teaches nor suggests the required solid surfactants. Finally, Nguyen neither teaches nor suggests the claimed surfactants. Because the required surfactant is completely missing from these references, the combination of these references cannot yield the claimed nanoemulsions. Kenji cannot compensate for the fatal deficiencies of these references. First, relates to microemulsions, not nanoemulsions -- none of the applied art relates in any way to adding the required surfactants to produce a nanoemulsion. This is particularly true given that Tabibi relates to microemulsions, not nanoemulsions, and that Nguyen does not relate to nanoemulsions in any way -- Nguyen relates to a

completely different art, disclosing a water treatment process. In short, no teaching or suggestion exists to add the required solid surfactant to nanoemulsions.

Applicant's arguments are not persuasive. Instant claim requires surfactant which is solid at or less than 45 degree Celsius and there is no recitation of specific surfactants. The claims as recited read on any surfactant which has melting point less than 45 degrees Celsius. Ribier teaches oils and Tabibi teaches oils have surfactants, however, the reference does not preclude any specific surfactant, as such it can be interpreted that the surfactants that are solid at temperatures less than 40 degree Celsius would also be included in the combined teachings of Ribier and Tabibi, as such the argument that no solid surfactant has been taught by the prior art is not persuasive. Additionally, the claims as recited do not specify any surfactant, claims read on innumerable surfactants. With regard to Kenji's and Nguyen's references, it is to be noted these references were not cited for surfactant. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Response to Declaration

5. The declaration under 37 CFR 1.132 filed 12/19/08 is insufficient to overcome the rejection of claims 25-43 based upon rejections as set forth in the last Office action because:

Applicant has provided side by side comparison of prior art versus the claimed invention, however, the declaration provided is not sufficient to provide unexpected results as such the rejection will be maintained.

Applicant argues that ;

Comparative Composition A containing a liquid sugar surfactant was unstable after 1 month -- crystals were present in the composition and the size of the oily phase globules had increased demonstrating composition instability. (Rule 132 dec., par. 7). Moreover, the turbidity of the composition increased, particularly at increased temperatures. (Rule 132 dec., par. 7). After 2 months, the composition was completely unstable, making turbidity measurements impossible. (Rule 132 dec., par. 7). In stark contrast, Invention Compositions B and C containing solid sugar surfactant were stable, even after 2 months, and these compositions had low and stable turbidity characteristics, even at increased temperatures. (Rule 132 dec., par. 8). This vast difference in physical properties among Comparative Composition A and Invention Compositions B and C was surprising and unexpected given the similarity of the compositions (the only noticeable difference being the use of a solid sugar surfactant as opposed to a liquid sugar surfactant. (Rule 132 dec., par. 9).

Applicant's arguments are not persuasive. The declaration comprises 4.5% of specific surfactant such as sucrose palmitostearate where as the claims as recited read on any surfactant that is solid at a temperature of 45 degrees Celsius which includes innumerable list of surfactants, as such the declaration is not commensurate with the scope of the claims. The claims are very broad in scope. Second, the limitation of surfactant being solid at temperature less than or equal to 45 degrees Celsius is very confusing and not explicit. The limitation as recited reads on any surfactant which has melting point of less than 45 degree Celsius will read on the claimed surfactant and such is not the case as per the disclosure. The disclosure does not support such surfactants. Applicant has only substantiated the results with specific surfactant, as

such the claims do not commensurate with the scope of declaration. Applicant has provided comparison of results with only one of the examples from Ribier, however, Ribier teaches multiple examples; see columns 5 and 6 of Ribier. Comparison does not call for picking and choosing from prior art, it is rather comparison of the whole prior art versus the claimed invention.

In response to transparency in composition, Ribier does teach in column 2, lines 5-10. It should also be noted that no specific components or amounts have been recited in claim 1. The claimed amount of surfactant in claim 27 is from 0.2 to 15%; however, the declaration only provides data with 4.5%. As such no effect of surfactant has been shown for the lower limits. As such the declaration is insufficient to overcome the rejections.

Applicant argues that:

The improved stability and turbidity properties obtained with Invention Compositions B and C are representative of the present invention. (Rule 132 dec., par. 9). Moreover, the improved stability and turbidity properties associated with the invention compositions would be commercially significant – compositions containing such improved properties would be more appealing to consumers because, for example, more transparent (less turbid) products are generally perceived by consumers as being more pure and, thus, as being more desirable, and because stable products maintaining their original characteristics (and containing minimal crystals) over an extended period of time are also more desirable to consumers. (Rule 132 dec., par. 11). Thus, the benefits associated with the claimed invention requiring the presence of a solid sugar surfactant are unexpected and surprising, and could not have been suggested by the applied art. In other words, one of ordinary skill in the art, seeking to produce a nanoemulsion, would not have been motivated to use a solid sugar surfactant in the nanoemulsion with the expectation or belief that a stable, unturbid nanoemulsion would result – such results were surprising and unexpected. Accordingly, the claimed invention cannot be obvious over the applied art.

Applicant argues that the improved turbidity properties would be more appealing to consumers which an unexpected property and thus the rejection shall be withdrawn. Applicants arguments are not persuasive because being more appealing is a relative term and what is more appealing to one person ,may not be appealing to another. Furthermore, the results of being more appealing does not obviate the obviousness rejection since the combination of teachings of prior art makes the claimed invention obvious to one of ordinary skill in the art.

6. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-

272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore /

Primary Examiner, Art Unit 1612